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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
LEE, SHUN K

ART UNIT	PAPER NUMBER
2878	

DATE MAILED: 07/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,930	EKDAHL ET AL.	
	Examiner	Art Unit	
	Shun Lee	2878	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-27,29 and 30* is/are rejected.

7)☒ Claim(s) *28 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

National Stage Application

1. The Examiner acknowledges consideration of the International Preliminary Examination Report in International Application PCT/SE99/01541. MPEP § 1893.03(e).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14, 15, 18-20, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Jensen (US 4,366,384).

In regard to claim **14**, it should be noted that the preamble has not been given patentable weight since the intended use of determining the presence of the fluid conduit at a predetermined location does not result in a structural difference between the claimed invention and the prior art (*i.e.*, a preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference between the claimed invention and the prior art; see MPEP 2111.02). Jensen discloses (Fig. 3 and 4) an apparatus for determining at least one characteristic of the contents of a fluid conduit, said apparatus comprising:

(a) a light source (36) for generating radiated light in a direction towards said predetermined location, whereby when said fluid conduit (28) is present at said predetermined location said radiated light passes in a direction through said fluid conduit (28),

(b) a first optical sensor (38) for detecting said radiated light passing through said fluid conduit (28), and

(c) a second optical sensor (40) for detecting said radiated light which is reflected by said fluid conduit (28).

In regard to claim **18** which is dependent on claim 14, Jensen also discloses (column 2, lines 36-48; Figs. 1, 3, and 4) a housing (14), and wherein said light source

(36), said first optical sensor (38) and said second optical sensor (40) are disposed in said housing (14).

In regard to claim **15** (which is dependent on claim 14), and claim **19** (which is dependent on claim 18), Jensen also discloses (column 2, lines 36-48; Fig. 1) a control device (14).

In regard to claim **20** which is dependent on claim 19, Jensen also discloses (column 2, lines 36-48; Fig. 1) that said housing (14) constitutes a portion of said control device (14).

In regard to claim **27** which is dependent on claim 15, Jensen also discloses (Fig. 4) that said control device (14) includes a control unit (50), and wherein said first (38) and second (40) optical sensors are electrically connected to said control unit (50), said first optical sensor (38) providing a first signal and said second optical sensor (40) providing a second signal.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (US 4,366,384) in view of Plotkin (US 5,928,179).

In regard to claim **16** which is dependent on claim 15, the apparatus of Jensen lacks that said control device comprises a device for the extracorporeal treatment of blood. Devices for the extracorporeal treatment of blood are well known in the art. For example, Plotkin teaches (column 1, line 11 to column 2, line 7) that devices (*e.g.*, a heart-lung machine) comprising of an oxygenator and an arterial filter (*i.e.*, hemodialysis) for the extracorporeal treatment of blood are used for extracorporeal perfusion during open-heart surgery. Plotkin teaches (column 3, lines 3-10) that an air-in-line detector can also be incorporated in order to automate elimination of air. Therefore it would have been obvious to one having ordinary skill in the art to incorporate the apparatus of Jensen into a device for the extracorporeal treatment of blood, in order to automate elimination of air in the device for the extracorporeal treatment of blood.

In regard to claim **29** which is dependent on claim 15, the apparatus of Jensen lacks that said control device comprises a dialysis monitor. It is noted that a dialysis monitor is defined in the specification as a detector such as an air-in-line detector for a blood dialysis (*i.e.*, hemodialysis) system. Further, devices for the extracorporeal

treatment of blood are well known in the art. For example, Plotkin teaches (column 1, line 11 to column 2, line 7) that devices (*e.g.*, a heart-lung machine) comprising of an oxygenator and an arterial filter (*i.e.*, hemodialysis) for the extracorporeal treatment of blood are used for extracorporeal perfusion during open-heart surgery. Plotkin teaches (column 3, lines 3-10) that an air-in-line detector can also be incorporated in order to automate elimination of air. Therefore it would have been obvious to one having ordinary skill in the art to incorporate the apparatus of Jensen into a device for the extracorporeal treatment of blood as a dialysis monitor, in order to automate elimination of air during arterial filtering (*i.e.*, hemodialysis).

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (US 4,366,384) in view of Havens *et al.* (US 5,319,182).

In regard to claim **17** which is dependent on claim 14, the apparatus of Jensen lacks that said second optical sensor is integrally formed with said light source. Integrated source-detectors are well known in the art. For example, Havens *et al.* teach (column 1, line 8 to column 4, line 2) it is known in the art integrated source-detectors have an inherently high signal-to-noise ratio. Jensen teaches (column 3, lines 9-17) that the second optical sensor (40) can be positioned (*e.g.*, adjacent to light source) on an arc between light source (36) and first optical sensor (38). Therefore it would have been obvious to one having ordinary skill in the art to provide an integrated source-detector as the adjacent light source (36) and second optical sensor (40) in the apparatus of Jensen, in order to obtain a high signal-to-noise ratio.

10. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (US 4,366,384) in view of Orndal *et al.* (US 4,797,655).

In regard to claim **21** which is dependent on claim 14, the apparatus of Jensen lacks a first waveguide for transmitting said radiated light from said light source to said predetermined location and for transmitting said radiated light reflected by said conduit to said second optical sensor, and a second waveguide for transmitting said radiated light which passes through said fluid conduit to said first optical sensor. Orndal *et al.* teach (column 3, lines 45-63; Fig. 2) to provide waveguides (*i.e.*, means for conducting light 17, 18, 19) in order to position the light source (*i.e.*, transmitter 15) and optical sensor (*i.e.*, receiver 16) on the same plane while directing the light from the light source to the optical sensor with a simple overall design and minimize external light interference. Therefore it would have been obvious to one having ordinary skill in the art to provide waveguides in the apparatus of Jensen, in order to direct the light from the light source to the optical sensors while positioning the light source and optical sensors on the same plane so as to minimize external light interference and to achieve a simple overall design.

In regard to claim **22** which is dependent on claim 21, Jensen is applied as in claim 15.

In regard to claim **23** which is dependent on claim 22, Jensen also discloses (column 2, lines 36-48; Figs. 1, 3, and 4) a housing (14), and wherein said light source (36), said first optical sensor (38), and said second optical sensor (40) are disposed in said housing (14), and including a fluid conduit holder (24a, 24b) for holding said fluid

conduit (28) at said predetermined location, said fluid conduit holder (24a, 24b) disposed on said housing (14). The apparatus of Jensen lacks said first and second waveguides being integrated with said fluid conduit holder. Orndal *et al.* teach (column 3, lines 45-63; Fig. 2) to provide waveguides (*i.e.*, means for conducting light 17, 18, 19) integrated with the fluid conduit holder in order to position the light source (*i.e.*, transmitter 15) and optical sensor (*i.e.*, receiver 16) on the same plane while directing the light from the light source to the optical sensor with a simple overall design and minimize external light interference. Therefore it would have been obvious to one having ordinary skill in the art to provide waveguides in the apparatus of Jensen, in order to direct the light from the light source to the optical sensors while positioning the light source and optical sensors on the same plane so as to minimize external light interference and to achieve a simple overall design.

In regard to claim **24** which is dependent on claim 22, the apparatus of Jensen lacks that said first waveguide is disposed at a location adjacent to said fluid conduit whereby an air gap is created therebetween. Orndal *et al.* teach (column 5, lines 49-53) that the tube should be "loose" within the holder in order not to deform the tube so as to obtain the same measured value every time under the same conditions. Inherent in a tube loose within a holder is an air gap between the loose tube and the holder. Therefore it would have been obvious to one having ordinary skill in the art to provide an air gap around the tube in the apparatus of Jensen, in order not to deform the tube so as to obtain the same measured value every time under the same conditions.

11. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (US 4,366,384) in view of Orndal *et al.* (US 4,797,655) and Deckert *et al.* (US 4,681,563).

In regard to claims **25** and **26** which are dependent on claim 14, Jensen also discloses (column 3, lines 3-6) that said light source (36) comprises an infrared light source. The apparatus of Jensen lacks that said light source generates said radiated light having a predetermined wavelength and a predetermined modulation (*e.g.*, a substantially square pulse sequence). Orndal *et al.* teach (column 5, lines 34-44) that the light should having a predetermined wavelength in order to transmit the light through the tube. Deckert *et al.* teach (column 9, lines 20-27) that the light should having a predetermined modulation of on and off (*i.e.*, a substantially square pulse sequence) in order to minimize the effect of ambient light. Therefore it would have been obvious to one having ordinary skill in the art to provide a predetermined wavelength and a predetermined modulation (*e.g.*, a substantially square pulse sequence) for the light in the apparatus of Jensen, in order to transmit the light through the tube and minimize the effect of ambient light.

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (US 4,366,384) in view of Crouse *et al.* (US 4,884,065).

In regard to claim **30**, Jensen disclose (Figs. 3 and 4; column 1, line 43 to column 2, line 12) a method for determining at least one characteristic of said contents of a fluid conduit, said method comprising directing radiated light towards said predetermined location whereby when said fluid conduit is present at said predetermined location said

radiated light passes in a direction through said conduit, detecting a first portion of said radiated light passing through said fluid conduit and detecting a second portion of said radiated light which is reflected by said fluid conduit. The method of Jensen lacks determining the presence of the fluid conduit at a predetermined location. Crouse *et al.* teach (column 3, lines 34-36; column 6, line 65 to column 7, line 12) that a second sensor can be used to detect light reflected (*i.e.*, refracted) by the presence of a tube in order to verify that the tubing is properly situated. Therefore it would have been obvious to one having ordinary skill in the art that the second sensor (40) in the method of Jensen can be used to detect light reflected (*i.e.*, refracted 46) by the presence of a tube (28), in order to verify that the tubing is properly situated.

Allowable Subject Matter

13. Claims 28 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the instant application is deemed to be directed to an nonobvious improvement over the invention patented in US Patent 4,366,384. The improvement comprises in combination with other recited elements, that when said first signal is at a predetermined high level and said second signal is at a predetermined low level, said comparing means determines that said fluid conduit is not present at said predetermined location, when said first signal is at a predetermined medium level and said second signal is at a predetermined high level, said comparing means determines

that said fluid conduit is present at said predetermined location and said fluid is not present in said fluid conduit, when said first signal is at a predetermined high level and said second signal is at a predetermined high level, said comparing means determines that said fluid conduit is present at said predetermined location and said fluid comprises a transparent fluid, when said first signal is at a predetermined low level and said second signal is at a predetermined high level, said comparing means determines that said fluid conduit is present at said predetermined location and said fluid comprises an opaque fluid, when said first signal is at a predetermined low level and pulses at a predetermined high level, and said second signal is at a predetermined high level, said comparing means determines that said fluid conduit is present at said predetermined location and said fluid comprises an opaque fluid containing air bubbles, and when said first signal is at a predetermined low or medium level and said second signal is at a predetermined low level, said comparing means determines that an error condition exists as recited in claims 28 and 31.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shun Lee whose telephone number is (703) 308-4860. The examiner can normally be reached on Tuesday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Font can be reached on (703) 308-4881. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

CONSTANTINE HANNAHER
PRIMARY EXAMINER
GROUP ART UNIT 2878

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July 17, 2002